

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF MISSISSIPPI  
OXFORD DIVISION

ROY WILMOTH, JR.

PLAINTIFF

V.

CIVIL ACTION NO. 3:20-cv-120-NBB-RP

ALEX M. AZAR, II, in his Official  
Capacity as Secretary of the U.S.  
Department of Health and Human Services

DEFENDANT

**MEMORANDUM OPINION**

Presently before the court is the motion of the defendant Alex M. Azar, Secretary of the United States Department of Health and Human Services, to dismiss this action under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Upon due consideration of the motion, response, and applicable authority, the court is ready to rule.

**Factual and Procedural Background**

The plaintiff, Roy Wilmoth, Jr., is a Medicare beneficiary who is challenging a decision of the Medicare Appeals Council (“MAC”) denying coverage for the lease of a medical device manufactured and supplied by Novocure, Inc., which is not a party to this action, for the period of April 19, 2018 through June 19, 2018. Wilmoth alleges in his Amended Complaint that he was diagnosed with glioblastoma, a type of brain tumor, in February 2016, for which he was prescribed tumor treatment field therapy (“TTFT”), a treatment delivered through equipment known as the Optune System from Novocure.

Wilmoth alleges that after a series of favorable ALJ decisions finding the Optune System covered by Medicare for certain periods of the plaintiff’s treatment, an ALJ issued a decision on May 7, 2019, holding the TTFT treatment “not medically reasonable or necessary” and therefore

not a covered Medicare benefit.<sup>1</sup> Wilmoth was therefore denied coverage for the April to June 2018 period. Wilmoth appealed to the MAC, arguing that the Secretary was collaterally estopped from relitigating the coverage issues based on the prior favorable decisions finding coverage for other treatment periods. The MAC agreed with the ALJ and issued an opinion on October 15, 2019, adopting the ALJ's decision. The MAC, however, held the supplier, Novucure, financially responsible for the non-covered costs and did not hold Wilmoth financially responsible for any non-covered costs. It is uncontested that Wilmoth has no legal liability for the charges.

Wilmoth then filed the present action under 42 U.S.C. § 405(g) seeking judicial review of the MAC's October 15, 2019 decision. The Secretary has now moved to dismiss the Amended Complaint under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) on grounds that Wilmoth lacks standing because he has not suffered an actual injury and because the Amended Complaint fails to allege facts that state a cognizable claim.

#### Standard of Review

##### **Federal Rule of Civil Procedure 12(b)(1)**

As courts of limited jurisdiction, federal courts acquire jurisdiction only by statute or through the United States Constitution. *In re FEMA Trailer*, 668 F.3d 281, 286 (5th Cir. 2012); *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). The court must dismiss a case when the plaintiff fails to establish subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). A case is properly dismissed for lack of subject matter jurisdiction when the court lacks the statutory or constitutional power to adjudicate the case. *Home Builders Ass'n of Miss., Inc. v.*

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<sup>1</sup> Under 42 U.S.C. § 1395y(a)(1)(A) of the Medicare statute, "no payment may be made under ... part B of this subchapter for any expenses incurred for items or services [] which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member ...." 42 U.S.C. § 1395y(a)(1)(A).

*City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998). The burden of establishing federal jurisdiction rests on the party seeking the federal forum. *Stockman v. Fed. Election Comm’n*, 138 F.3d 144, 151 (5th Cir. 1998). A district court may determine its jurisdiction based on: “the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts plus the court’s resolution of disputed facts.” *Ramming v. United States*, 281 F.3d 158, 162 (5th Cir. 2001).

**Federal Rule of Civil Procedure 12(b)(6)**

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* A court must accept all well-pleaded facts as true and must draw all reasonable inferences in favor of the plaintiff. *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 232-33 (5th Cir. 2009). The court is not, however, required to accept as true conclusions of law, conclusory allegations, unreasonable inferences, or unwarranted deductions of fact. *Harold H. Huggins Realty, Inc. v. FNC, Inc.*, 634 F.3d 787, 796 (5th Cir. 2011).

A legally sufficient complaint must establish more than a “sheer possibility” that the plaintiff’s claim is true. *Iqbal*, 556 U.S. at 678. It need not contain detailed factual allegations, but it must go beyond labels, legal conclusions, or formulaic recitations of the elements of a cause of action. *Twombly*, 550 U.S. at 555. In other words, the face of the complaint must contain enough factual matter to raise a reasonable expectation that discovery will reveal evidence of each element of the plaintiff’s claim. *Lormand*, 565 F.3d at 255-57. If there are

insufficient factual allegations to raise a right to relief above the speculative level or if it is apparent from the face of the complaint that there is an insuperable bar to relief, the claim must be dismissed. *Twombly*, 550 U.S. at 555; *Jones v. Bock*, 549 U.S. 199, 215 (2007); *Carbe v. Lappin*, 492 F.3d 325, 328 & n.9 (5th Cir. 2007).

### Analysis

The Secretary asserts that this court lacks jurisdiction to grant Wilmoth any relief because Wilmoth has no legal obligation to pay the subject medical charges and therefore has not suffered any concrete injury sufficient to confer Article III standing. Article III, § 2, of the U.S. Constitution limits federal court jurisdiction to live “cases” or “controversies.” This is a “bedrock requirement.” *Raines v. Byrd*, 521 U.S. 811, 818 (1997) (quoting *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 471 (1982)). The “irreducible constitutional minimum” of standing consists of three elements: the plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the alleged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). The plaintiff bears the burden of establishing these elements. *Spokeo, Inc. v. Robbins*, 136 S. Ct. 1540, 1547 (2016).

Wilmoth first argues that the denial of his statutory right to Medicare benefits is sufficient to confer standing. In *Spokeo, Inc. v. Robbins*, 136 S. Ct. 1540, 1549 (2016), and more recently in *Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615, 1619 (2020), however, the Supreme Court made clear that an alleged violation of a statutory right alone – in the absence of any actual or imminent injury – does not satisfy Article III’s standing requirement.

In *Spokeo*, the plaintiff alleged that the operator of a website known as a “people search engine” violated the Fair Credit Reporting Act because search results contained inaccurate

information about him. *Spokeo*, 136 S. Ct. at 1546. The district court dismissed the complaint because the plaintiff had not alleged an injury-in-fact. *Id.* The Ninth Circuit reversed, finding that Spokeo had violated the plaintiff's statutory rights and that the plaintiff had a personal interest in the handling of his credit information. *Id.* at 1545-46. The Supreme Court reversed the Ninth Circuit, holding that while it is possible for an intangible injury to satisfy the injury-in-fact component of standing, "Congress cannot erase Article III's standing requirements by statutorily granting the right to sue to a plaintiff who would otherwise not have standing." *Id.* at 1548.

In *Thole*, the Supreme Court reiterated that a statutory violation without an actual or imminent injury cannot confer Article III standing. The plaintiffs in *Thole* were participants in a defined benefit retirement plan who alleged the defendants mismanaged the plan and who sought an order requiring the defendants to reimburse the plan for its losses caused by their malfeasance. *Thole*, 140 S. Ct. at 1619. The Court noted the plaintiffs had received all the retirement benefits they were entitled to thus far, and because they were legally and contractually entitled to receive the benefits for the rest of their lives regardless of the value of the plan or the investment decisions of the plan's fiduciaries, the plaintiffs were not likely to suffer a reduction of their benefits in the future. *Id.* at 1618. The plaintiffs argued that they had standing because ERISA gives participants a cause of action for restoration of plan losses and other equitable relief. *Id.* at 1620. The Court, however, found the ERISA provision insufficient to confer standing because the plaintiffs had not suffered a concrete injury. *Id.* at 1619-20.

Wilmoth cites three Supreme Court cases which he contends stand for the proposition that Congress may create a statutory right or entitlement the alleged deprivation of which can confer standing even in the absence of a judicially cognizable injury: *Warth v. Seldin*, 422 U.S.

490 (1975); *Linda R.S. v. Richard D.*, 410 U.S. 614 (1973); and *Heckler v. Ringer*, 466 U.S. 602 (1984). This court finds that these cases do not support Wilmoth’s position.

In *Warth*, the plaintiffs, taxpayers and low-income residents and various organizations in Rochester, New York, alleged that an adjacent town’s zoning ordinances violated the Constitution and federal civil rights laws because the ordinances effectively excluded low and moderate-income persons from living in the town. *Warth*, 422 U.S. at 493-95. The Supreme Court affirmed the district court’s dismissal based on lack of standing, reasoning that “Congress may grant an express right of action to persons who otherwise would be barred by prudential standing rules. Of course, Article III’s requirement remains: *the plaintiff still must allege a distinct and palpable injury to himself ....*” *Id.* at 501 (emphasis added). Contrary to Wilmoth’s assertion, therefore, *Warth* does not stand for the proposition that Congress can vitiate Article III’s injury-in-fact standing requirement.

*Linda R.S. v. Richard D.* involved a constitutional challenge to a state criminal statute by a woman who alleged that she could obtain child support for her illegitimate child if the statute were declared unconstitutional. *Linda R.S.*, 410 U.S. at 615. Wilmoth cites a footnote from the case in support of his position that “Congress may enact statutes creating legal rights, the invasion of which creates standing, even though no injury would exist without the statute.” *Id.* at 617, n.3. This footnote is in the middle of a paragraph noting the confusing state of the law on standing. The paragraph ends by acknowledging the importance of the actual or imminent injury component of Article III standing: “Although the law of standing has been greatly changed in the last 10 years, we have steadfastly adhered to the requirement that, at least in the absence of a statute expressly conferring standing, federal plaintiffs must allege some threatened or actual

injury resulting from the putatively illegal action before a federal court may assume jurisdiction.”  
*Id.* at 617.

Finally, in *Heckler v. Ringer*, the plaintiffs were Medicare claimants challenging the Secretary’s ruling that the type of surgery they had undergone was not reasonable and necessary. *Heckler*, 466 U.S. at 602. One of the plaintiffs alleged that the Secretary’s decision precluded him from having the surgery, and he sought an injunction requiring the Secretary to reverse his decision. *Id.* at 604. The Court interpreted the plaintiff’s claim as essentially one requesting the payment of future benefits. *Id.* at 620-21. The Court then held that Congress clearly foreclosed the possibility of declaratory judgment actions in this context because they would bypass the exhaustion requirements of the Medicare Act, which provides that a claim be filed only after a medical service is provided. *Id.* at 621. The Court declined to sanction a bypass of the statutory scheme via a judicial advisory opinion. *Id.* at 621-22 (“Congress clearly foreclosed the possibility of obtaining such advisory opinions from the Secretary herself, requiring instead that a claim could be filed for her scrutiny only after the medical service for which payment is sought has been furnished. Under the guise of interpreting the language of § 405(h), we refuse to undercut the choice by allowing federal judges to issue such advisory opinions.”) (internal citations omitted). The Court found that because the plaintiff had not satisfied the non-waivable exhaustion requirements of 42 U.S.C. § 405(g), the federal court lacked jurisdiction over the claim. *Id.* at 626-27. *Heckler*, therefore, like *Warth* and *Linda R.S. v. Richard D.*, does not support Wilmoth’s argument that the Medicare Act’s authorization for a dissatisfied beneficiary to sue in federal court, in the absence of an actual injury, is sufficient to confer standing.<sup>2</sup>

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<sup>2</sup> Wilmoth also cites a number of out-of-circuit district court cases in support of his position, but these cases predate the Supreme Court’s clarifications in *Spokeo* and *Thole* regarding standing requirements and are also distinguishable from the present case. This court, therefore, finds them unpersuasive.

Having found Wilmoth’s argument based on statutory entitlement unpersuasive, the court now turns to his alternative argument: that he meets the injury-in-fact requirement because, if the denial of the subject claim is not reversed, he could be made liable for future claims, have treatment conditioned on his personal liability, and/or be charged with present knowledge of the denial, thereby precluding recovery on future claims. This argument is without merit. As the Secretary notes, Wilmoth does not know if his future claims will be denied; and in fact, he alleges his subsequent claims have been paid. [Docket 33, pp. 6-8.] Any relationship between the subject claim denial and Wilmoth’s financial liability for any future medical charges is speculative. Equating speculative future harm with concrete injury is inconsistent with Article III standing jurisprudence. *See, e.g., Clapper v. Amnesty International USA*, 568 U.S. 398, 409 (2013) (“Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes – that the injury is *certainly* impending.”).

In the present case, not only is the alleged harm speculative, Wilmoth’s speculation is inconsistent with the facts of this case. As noted, Wilmoth’s claims subsequent to the claim denial at issue here have been paid. Further, the Local Coverage Determination<sup>3</sup> for the Optune System was revised in September 2019 to provide coverage. (The 2014 LCD, which was in effect when Wilmoth’s subject claim herein was denied, categorically denied coverage for TTFT.) As the Secretary notes, Wilmoth alleges injuries that are contingent on the actions of third parties. An ALJ reviewing a future claim would have to ignore the revised LCD, or

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<sup>3</sup> Local Coverage Determinations or “LCDs” are decisions made by a Medicare Administrative Contractor on whether to cover a particular item or service within the contractor’s jurisdiction in accordance with § 1862(a)(1)(A) of the Social Security Act.



Novocure would have to give Wilmoth an “advance beneficiary notice”<sup>4</sup> that would shift payment obligations for future treatments to Wilmoth, which to date it has not done, in order for Wilmoth to suffer an injury-in-fact. Because Wilmoth’s liability is dependent on not one, but a chain of decisions made by different actors, his alleged future harms are an “exercise in the conceivable” but do not make a “factual showing of perceptible harm” sufficient for Article III standing. *Lujan*, 504 U.S. at 566. The recent change in the LCD even further attenuates the potential for Wilmoth’s future liability for TTFT.

Wilmoth cites 42 U.S.C. § 1395pp as a vehicle to confer standing and to support his argument that he might be held personally liable for future claims. Section 1395pp(b) states that “in the case of *comparable situations* arising thereafter [the denial of benefits] with respect to such individual, he shall, by reason of such notice [from the Secretary] ... be deemed to have knowledge that payment cannot be made for such items or services.” 42 U.S.C. § 1395pp(b) (emphasis added). It is undisputed in the present case that a significant change was made between the 2014 LCD and the 2019 LCD, which provides coverage for TTFT when certain criteria are satisfied. It is speculative, and indeed quite unlikely, that an ALJ would deem Wilmoth to have knowledge that his future TTFT claims will be denied given the change in the 2019 LCD and the current lack of a “comparable situation” within the meaning of Section 1395pp. The court therefore finds that Section 1395pp does not confer Article III standing for the plaintiff.

The likelihood that any future claims of the plaintiff will be denied is minimal. Wilmoth cannot, therefore, establish a substantial probability that Medicare will deny any of these

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<sup>4</sup> An advance beneficiary notice or “ABN” is a document placing the beneficiary on notice that the claim may not be paid (or may not be paid in full) by Medicare and that, if so, the beneficiary will be personally liable for any amount left unpaid.

potential future claims. *See California Clinical Laboratory Ass’n v. Secretary of HHS*, 104 F. Supp. 3d 66 (D.D.C. 2015) (finding no injury-in-fact sufficient to satisfy Article III standing requirements where the plaintiffs failed to establish a substantial probability that Medicare would deny future coverage). If, however, certain future claims are denied and Wilmoth is subject to financial liability as a result, Wilmoth’s proper recourse would be to follow the appeals procedure at that point and file a new action in the district court, if necessary.

#### Conclusion

For the foregoing reasons, the court finds that the Secretary’s motion to dismiss is well taken and should be granted. A separate order in accordance with this opinion shall issue this day.

This 22nd day of February, 2021.

/s/ Neal Biggers

NEAL B. BIGGERS, JR.

UNITED STATES DISTRICT JUDGE